Remarks

In a Final Office Action, dated 11 Jan 2007, Claims 2 and 15 were describes as being allowed and claims 17, 19 and 21 were rejected under 35 U.S.C. § 112, 1st paragraph (written description and enablement) and 35 U.S.C. 103(a). In response, Applicants cancelled Claims 17, 19 and 22 in order to put the Application in condition for allowance. Subsequently, the Examiner contacted Applicants Attorney by phone to discuss the relation between the X-ray diffraction data of Claim 2 and "a hydrate, or mixtures thereof" of crystalline 2,5-dione-3-(1-methyl-1H-indol-3-yl)-4-[1-(pyridin-2-ylmethyl)piperidin-4-yl]-1H-indol-3-yl]-1H-pyrrole mono-hydrochloride. On 3 May 2007, an Advisory Action was issued wherein Claims 2 and 15 were apparently rejected on the following ground:

> *"Continuation of 11, does NOT place the application in condition for allowance because: The X-ray diffraction data disclosed in claim 1 does not explain the hydrates and esters of the compounds. Applicant is requested to explain the data in claim 1."*

Applicants respectfully point out that while the advisory action states that the X-ray diffraction data disclosed in "claim 1" does not explain the "hydrates and esters" of the crystalline 2,5-dione-3-(1-methyl-1H-indol-3-yl)-4-[1-(pyridin-2-ylmethyl)piperidin-4-yl]-1H-indol-3-yl]-1H-pyrrole mono-hydrochloride, the claim actually under consideration is Claim 2. In fact, Claim 1 was previously cancelled and never recited X-ray diffraction data. Further, Claim 2 does not recite "hydrates and esters," but rather "a hydrate thereof, or mixtures thereof." For purposes of response, applicants assume in good faith that these inconsistencies are simply unintended errors of transcription in the Advisory Action.

Section 706.07(a) of the MPEP states:

> *"Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)."*

Since Claims 2 and 15 had not been previously rejected during prosecution of this application, it was improper to reject them for the first time in an Advisory Action after final. Applicants were fully responsive to the Final Office action, which indicated that Claims 2 and 15 were allowed and claims 17, 19 and 21 were rejected. Since Applicants response was merely to cancel the

rejected claims, the new ground for rejection could not possibly have been *"necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement."* [See Section 706.07(a) of the MPEP] As such, the present rejection is improper as issued and should be either withdrawn or reissued in a new, non-final Office Action with an accompanying 3-month response period.

Nevertheless, in order to resolve the Examiner's issues and expedite prosecution, Applicants' Attorney contacted the Examiner by phone on 10 Jul 2007 and discussed the current amendment to Claim 2, wherein the phrase "a hydrate thereof, or mixtures thereof" is excised. In view of this amendment, Applicants respectfully submit that Claims 2 and 15 set forth an invention that is new, useful, and unobvious, and which is therefore deserving of patent protection. Passage to Issue of the present application is believed to be in order, and is respectfully requested.

Please charge any fees or credit any overpayment in connection with this application which may be required by this or any related paper to Deposit Account No. 05-0840.

If the Examiner has any questions, or would like to discuss any matters in connection with this application, he or she is invited to contact the undersigned at (317) 276-0307.

Respectfully submitted,

/John A. Cleveland, Jr., Ph.D./

John A. Cleveland, Jr., Ph.D.
Attorney for Applicants
Registration No. 50,697
Phone: 317-276-0307

Eli Lilly and Company
Patent Division/
P.O. Box 6288
Indianapolis, Indiana 46206-6288
July 11, 2007